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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,003	11/16/2001	Carl Alexander Kamb	29345/36971A	6935

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Joseph A. Williams, Jr. Ph.D.
Marshall, Gerstein, & Borun
6300 Sears Tower
233 South Wacker Drive
Chicago, IL 60606-6402

EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/991,003	KAMB ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on th cover sh t with th correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24 and 51* is/are pending in the application.

4a) Of the above claim(s) *25-50 and 52-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a)☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *03/29/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Change of Art Unit

Please note that this application has been forwarded to Art Unit 1654, Examiner Audet. All future correspondence should be so directed.

Election/Restrictions

Applicant's election **without** traverse of Group I, claims 1-24 and 50-51, in the paper filed October 17, 2003, is acknowledged. However, upon examination of the claims by the new examiner, it was determined that a further restriction was necessary, namely, restriction of claim 50 (formerly of elected Group I). For clarity, this additionally restricted group will be identified as Group VI, as a continuation of the previous restriction requirement.

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept.

In accordance with 37 CFR 1.142, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

VI. Claim 50, drawn to a method of making *any* polypeptide having viral activity, classified in class 530, subclass 300+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be

used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the method of making (Invention VI) can be used to make any polypeptide having viral activity, not just cW985 polypeptides (Invention I).

Inventions II-IV and VI are unrelated. Inventions II-V do not involve polypeptides having viral activity.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of making of Invention VI is drawn to making any polypeptide with viral activity, while Invention I is drawn only to the use of cW985 polypeptides in methods of treatment.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference, which would anticipate the invention of one group, would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Restriction for examination purposes is therefore proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CRF 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

During a telephone conversation with Lynn Janulis, Attorney for Applicant, on December 5, 2003, a provisional election was made without traverse to prosecute the invention of Group I, amended to include claims 1-24 and 51. Affirmation of this election must be made by applicant in replying to this Office action. Based on the amended restriction, claims 25-50, and 52-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention (Group I, claims 1-24 and 51), there being no allowable generic or linking claim.

Information Disclosure Statement

The information disclosure statement filed March 29, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Namely, the "other documents" were not found to be scanned into the electronic file wrapper, and the references were not found in the parent file 09/259155 or the grandparent file 08/812994.

Claim Objections

The claims are objected to because they include reference characters which are not enclosed within parentheses. In claims 1-24 and 51, the polypeptide sequence is identified by Figure 11 and (cW985). Based on Figure 11, the polypeptide sequence is SEQ ID NO: 8. It is suggested that the claims be drawn to SEQ ID NO: 8 and, if still desired, Figure 11 and identifier cW985 be put in parenthesis (or cancelled from the claims).

Reference characters corresponding to elements recited in the detailed description of the drawings and used in conjunction with the recitation of the same element or group of elements in the claims should be enclosed within parentheses so as to avoid confusion with other numbers or characters which may appear in the claims. See MPEP § 608.01(m).

Reference to Figures or Tables

> Where possible, claims are to be complete in themselves. *Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience.*" Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted)(emphasis added). MPEP 2173.05(s).
>
> The use of reference characters is to be considered as having no effect on the scope of the claims. MPEP § 608.01(m).

Claims 3 and 5 are objected to for being independent claims beginning with "The". These claims should being with "An".

Claim 5 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 2. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112 1st Scope

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-24 and 51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 8 (Figure 11), does not reasonably provide

enablement for any "biologically active *modification or fragment*", namely what % modification and what specific fragments, of SEQ ID NO: 8 that "display viral activity". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

> The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement for any "biologically active modification or fragment" of SEQ ID NO: 8, that "display viral activity" for the following reasons.

The nature of the invention: The claimed invention is generally drawn to any "biologically active modification or fragment" of SEQ ID NO: 8, including those that "display viral activity" (i.e. claim 1).

The state of the prior art and the predictability or lack thereof in the art:

SEQ ID NO: 8 is small peptide (53 residues), and it is well known in the art that even a slight change in the structure of a peptide, especially a small peptide, can drastically alter its native function. Factors such as stearic hindrance, change in polarity or conformation of the peptide leads to the change in the peptide structure and can affect its native function.

The amount of direction or guidance present and the presence or absence of working examples: Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). Applicants have reasonably taught and/or demonstrated SEQ ID NO: 8. However, the specification has not adequately described all the "biologically active modification[s] or fragment[s]" of SEQ ID NO: 8, clearly to show that they "display viral activity".

Furthermore, the specification and claims teach a "biologically active *modification*" of SEQ ID NO: 8 (Figure 11), but it is unclear if this includes conservative, or non-conservative substitutions, or any other chemical modification of SEQ ID NO: 8. Although specification pages 27-28 discuss "chemical modifications", the end-product structures of such modifications have not been described. Claims 6-10 describe that modifications that comprise a sequence 80-99% identical to SEQ ID NO: 8. Claim 12 is "a closely related analog" of SEQ ID NO: 8, that displays viral activity. Claim 13 is an "antigenic analog" of SEQ ID NO: 8, that binds to an antibody specific to SEQ ID NO: 8. Claim 21 is a "chemically modified" SEQ ID NO: 8. Other than SEQ ID NO: 8, the scope of what modifications thereof that will clearly display viral activity, is not described.

Additionally, the specification and claims teach a "biologically active *fragment*" of SEQ ID NO: 8 (Figure 11), but it is unclear what Applicant contemplates as the invention, of the 53 residue SEQ ID NO: 8, namely a 1-residue fragment, a 52-residue fragment or anything in between. The specification defines (page 12) that:

> The term "fragment" refers to any portion of a proteinaceous perturbagen that is at least 3 amino acids in length, or any RNA molecule that is at least 5 nucleotides in length. The descriptors "biologically relevant" or "biologically active" refer to that portion of a protein or protein fragment, RNA or RNA fragment, or DNA fragment that encodes either of the two previous entities, that is responsible for an observable phenotype, some portion of an observable phenotype, or for activation of a correlative reporter construct.

Specification page 25-26, further discusses, but does not specifically describe the structures of the "biologically active *fragments*". The specific residues that constitute the fragments have not been described or claimed. Claim 11 describes a "biologically active fragment" of SEQ ID NO: 8, but it is unclear what fragment(s) constitute a "biologically active fragment"? Claim 14-17 comprise any C and N-terminal fragments of SEQ ID NO: 8, or comprising at least 10 amino acids thereof. Other than SEQ ID NO: 8, the scope of what fragments will clearly display viral activity, is not described.

The breadth of the claims and the quantity of experimentation needed: The claims are broadly drawn to any "biologically active modification or fragment" of SEQ ID NO: 8, that "display viral activity". Based on the highly unpredictable and complex nature of peptide synthesis and function, determining which peptides could be made to correspond to the broad

claim 1, namely any "biologically active modification or fragment" of SEQ ID NO: 8, that "display viral activity" would require undue experimentation without a reasonable expectation of success by one of skill in the art.

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-24 and 51, it is unclear what is meant by the term "viral activity"? As claimed, the term is ambiguous and could mean viral enhancing or antiviral activity. It is suggested that the claims be amended to distinctly claim what type of viral activity the isolated polypeptide confers.

In claims 1-24 and 51, it is unclear what is further contemplated by the transitional phrase "comprising"? Namely, if the polypeptide is isolated, what else does the sequence comprise than the specified sequence? It was not found in the specification what additional residues are contemplated with SEQ ID NO: 8. It is suggested that the transitional phrase be amended to "consisting of".

In claim 3, it is unclear what is further contemplated by the transitional phrase "consisting essentially of"? One does not know what additional residues are contemplated with Figure 11 (cW985), SEQ ID NO: 8. It was not found in the specification what additional

residues are contemplated with SEQ ID NO: 8. It is suggested that the transitional phrase be amended to "consisting of".

In claims 18-20, it is unclear what is contemplated by a "heterologous sequence" (claim 18), wherein the heterologous sequences is a "scaffold" (claim 19); a "fluorescent protein" (claim 20)? Specification pages 26-27 discuss, but do not distinctly describe the structures of a "heterologous sequence". Thus, it is unclear what sequences are contemplated as capable of being fused to SEQ ID NO: 8, as part of the invention. Assuming support may be found, it is suggested that Applicant distinctly claim the heterologous sequence, i.e. by structure, in order that a search of the fused polypeptide, if necessary, may be conducted and so that any infringer may be put on notice as to what constitutes an infringement thereof.

Conclusion

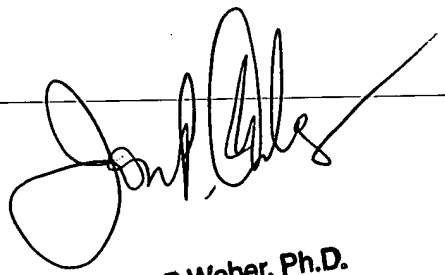
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA
December 23, 2003



Jon P. Weber, Ph.D.
Primary Examiner